PULMONARY VALVE IMPLANTATION • HYBRID STENT AORTIC ATRESIA ATRIAL EROSION BALLOON MITRAL VALVULOPLASTY • PDA CLOSURE • TRANSSEPTAL PUNCTURE ATRIAL SEPTUM • PULMONARY ARTERY INTERVENTION • TRICUSPID ATERSIA TYPE 1A • PERCUTANEOUS VALVE REPLACEMENT • STEM CELL THERAPY • CONGENITAL HEART DISEASE • PFO CLOSURE ANGIOPLASTY • PERCUTANEOUS ASD • COARCTATION STENTING • 3 DIMENSIONAL ROTATIONAL ANGIOGRAPHY • VENTRICULAR HYPERTROPHY • SEVERE HOMOGRAFT STENOSIS • TRANSHEPATIC LPA STENT • OCCLUDED FEMORAL VEINS • TRANSCATHETER PULMONARY VALVE IMPLANTATION • HYBRID STENT AORTIC ATRESIA • ATRIAL EROSION • TRANSCATHETER PULMONARY VALVE IMPLANTATION • PDA CLOSURE • TRANSSEPTAL PUNCTURE • ATRIAL SEPTUM • PULMONARY ARTERY INTERVENTION

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Indications: The Edwards SAPIEN XT transcatheter heart valve (THV) systems are indicated for use in pediatric and adult patients with a dysfunctional, non-compliant right ventricular outflow tract (RVOT) conduit with a clinical indication for intervention and: pulmonary regurgitation ≥ moderate and/or mean RVOT gradient ≥ 35 mmHg.

Contraindications: The THV and delivery systems are contraindicated in patients with inability to tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Assessment for coronary compression risk prior to valve implantation is essential to prevent the risk of severe patient harm. Incorrect sizing of the THV may lead to paravalvular leak, migration, embolization and/or RVOT rupture. Accelerated deterioration of the THV may occur in patients with an altered calcium metabolism. Prior to delivery, the THV must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. THV leaflets mishandled or damaged during any part of the procedure will require replacement of the THV. Do not use the THV if the tamper evident seal is broken, the storage solution does not completely cover the THV, the temperature indicator has been activated, the THV is damaged, or the expiration date has elapsed. Do not mishandle the NovaFlex+ delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. THV recipients should be maintained on anticoagulant/antiplatelet therapy as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solutions, or to the THV.

Precautions: Safety, effectiveness, and durability of the THV have not been established for implantation within a previously placed surgical or transcatheter pulmonic valve. Long-term durability has not been established for the THV. Regular medical follow-up is advised to evaluate THV performance. Glutaraldehyde may cause irritation of the skin, eyes, nose and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, immediately flush the affected area with water and seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Material Safety Data Sheet available from Edwards Lifesciences. Patient anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: Echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin or sensitivity to contrast media, which cannot be adequately premedicated; pregnancy; and patients under the age of 10 years.

Potential Adverse Events: Potential risks associated with the overall procedure including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, myocardium or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; embolization including air, calcific valve material or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect arrhythmia; arteriovenous fistula; reoperation or reintervention; ischemia or nerve injury; pulmonary edema; pleural effusion, bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma or ecchymosis; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; angina; fever. Additional potential risks associated with the use of the THV, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device malposition requiring intervention; valve deployment in unintended location; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; and mechanical failure of delivery system, and/or accessories.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN XT transcatheter heart valve for implantation.

Contraindications: No known contraindications.

Warnings: The device is designed, intended, and distributed for single use only. **Do not resterilize or reuse the device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device. Do not use the device if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

Precautions: For special considerations associated with the use of this device prior to THV implantation, refer to the SAPIEN XT transcatheter heart valve Instructions for Use.

Potential Adverse Events: No known potential adverse events.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.
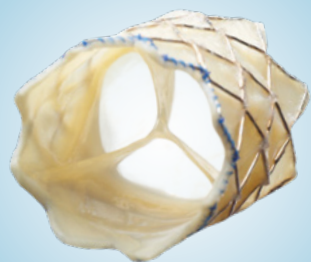
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Melody™
Transcatheter Pulmonary Valve (TPV) System
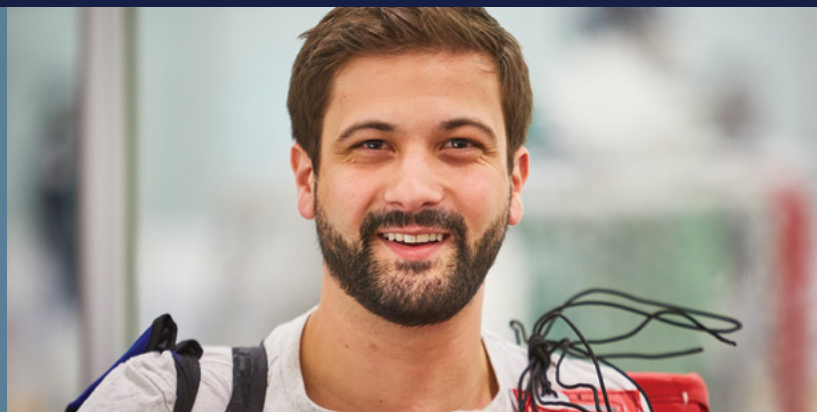
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The Melody TPV System received Health Canada approval in December 2006 and US approval under an HDE on January 25, 2010 (H080002).

PMA approval received January 27, 2015 (P140017).

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Melody™ Transcatheter Pulmonary Valve,
Ensemble™ II Transcatheter Valve Delivery System

Important Labeling Information for the United States

Indications: The Melody TPV is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has ≥ moderate regurgitation, and/or a mean RVOT gradient ≥35 mm Hg.

Contraindications: None known.

Warnings/Precautions/Side Effects:

- **DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.**

- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.

- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.

- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.

- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.

- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.

- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture,* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Important Labeling Information for Geographies Outside of the United States

Indications: The Melody™ TPV is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR

- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

Contraindications:

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath

- Implantation of the TPV in the left heart

- RVOT unfavorable for good stent anchorage

- Severe RVOT obstruction, which cannot be dilated by balloon

- Obstruction of the central veins

- Clinical or biological signs of infection

- Active endocarditis

- Known allergy to aspirin or heparin

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Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site.

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The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.

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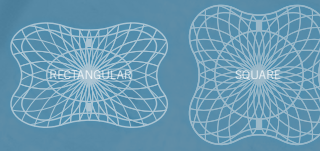
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W = Waist

T = Twist
Connection diameter is negligible

The Occlutech PLD is available with two types of connections between the discs, **W**aist or **T**wist. Example shown on a Occlutech PLD Square.

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Original Scientific Article

Portable Versus Mounted Fluoroscopic Imaging During Transcatheter Aortic Valve Replacement

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Abstract

Objectives: To compare outcomes of portable angiography system (PAS) versus mounted angiography system (MAS) in high-risk patients with severe symptomatic aortic stenosis (AS) undergoing transcatheter aortic valve replacement (TAVR).
Background: MAS is the preferred imaging modality for TAVR procedures. The role and safety of PAS have not been systematically studied in TAVR.
Methods: A retrospective study was conducted on 101 consecutive TAVR cases performed at our center from December 2014 to November 2016. Procedural, safety and clinical endpoints were compared at 30 days and 1 year.
Results: 24 patients were in the PAS group and 77 in the MAS group. There was no significant difference in all-cause mortality between the PAS and MAS group at 30 days (4.2% vs 2.6%, P = 0.56) or at 1 year (21.7% vs 16.0%, P = 0.54). The two study groups had comparable rates of ischemic stroke (PAS, 4.3% vs MAS, 1.3%, P = 0.42), life-threatening or major bleeding (16.7% vs 6.6%, P = 0.21), vascular complication requiring intervention (8.7% vs 5.3%, P = 0.62), pacemaker implantation (13.0 vs 6.7%, P = 0.39), rehospitalization (8.7% vs 18.7%, P = 0.35), improvement in New York Heart Association functional class (P = 0.17), and degree of paravalvular leak (P = 0.22). The PAS group more frequently underwent alternative vascular access (25.0% vs 1.3%, P = 0.001), which was associated with longer length of stay from procedure to discharge (3 days vs 2 days, P = 0.003). Total radiation exposure was significantly less in the PAS group (air kerma 371 mGy vs 683 mGy, P = 0.043).
Conclusions: PAS is a safe and effective imaging modality for TAVR procedures with less total radiation exposure than MAS.

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Key Words

Aortic stenosis • Transcatheter aortic valve replacement • Fluoroscopy • Mobile C-arm • Air kerma

Introduction

Transcatheter aortic valve replacement (TAVR) is preferred over surgical aortic valve replacement (SAVR) in patients with severe symptomatic aortic stenosis (AS) who are high-risk surgical candidates [1-6]. In this cohort of patients, large, multicenter, randomized clinical trials have demonstrated the non-inferiority of TAVR to SAVR for mortality and major cardiovascular and cerebrovascular adverse outcomes, as well as its superiority for major bleeding events [1-4, 7-9]. More recently, in intermediate surgical risk patients, several studies have shown the superiority of TAVR compared to SAVR for mortality, stroke, and moderate or severe aortic regurgitation at 1 year [10-13]. As a result of these investigations, TAVR is now a class IIa recommendation in patients

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with severe symptomatic AS who are at intermediate surgical risk [14].

Traditionally, TAVR procedure has been performed using a high resolution, multifunction, mounted angiography system (MAS), often utilizing computed tomography (CT) overlay technology to optimize valve positioning. A portable angiography system (PAS)—defined as a mobile C-arm fluoroscopic system capable of obtaining high quality angiographic images with cineography, digital subtraction, and archiving abilities [15-17]—is an alternative imaging modality that has been less commonly used in structural heart interventions. Instead, PAS has more frequently been utilized in endovascular, urologic, orthopedic and gastroenterology procedures [15, 18]. In the past, PAS has been limited by poor image resolution, small field of view, longer procedure times with frequent system overheating, and potential breach of sterility from C-arm rotation [19-22]. As a result, it has not been seen as a feasible alternative to current mounted camera use during TAVR [20]. However, with the recent production of digital, high-resolution, liquid cooled PAS, the new generation of portable imaging addresses many of these perceived limitations.

While PAS has been used during TAVR in select institutions outside the United States [23], to our knowledge, the role and safety of PAS have not been systematically studied in TAVR. Herein, we propose that the new generation of high-powered, high-resolution PAS may be implemented as a safe and feasible alternative to MAS. In this study, we compare clinical and procedural outcomes of high-risk patients with severe symptomatic AS undergoing TAVR using a traditional MAS versus a new generation PAS.

Methods

Study design

A retrospective study was conducted on 101 consecutive TAVR cases performed at our center from December 09, 2014 to November 15, 2016. The study was approved and performed in accordance with the hospital institutional review board at United Health Services Hospitals (UHSH) Wilson Medical Center, Johnson City, NY. Patients underwent transcatheter valve replacement for the treatment of severe symptomatic AS. All candidates received standard preoper-

ative evaluation by the institution's heart valve team, which consisted of cardiologists (valve specialists, imaging specialists, and interventionalists) and cardiothoracic surgeons. Operative risk was measured by the Society of Thoracic Surgeons (STS) predicted risk of mortality score, which was calculated using the online STS Adult Cardiac Surgery Risk Calculator [24]. Patients with a STS risk score of 3% or greater, or otherwise deemed at prohibitive risk for open surgical repair, were candidates for TAVR. The default vascular access route for transcatheter intervention was transfemoral. However, when the ileofemoral approach was unfeasible, an ideal alternative access (transaortic, transapical, or transsubclavian) was chosen based on individual patient anatomy.

TAVR procedures were performed using either a new generation PAS or a traditional MAS fluoroscopic camera, which were allocated in a randomized fashion based on hybrid operating room (OR) and camera availability. Pulsed fluoroscopy and cineography imaging modes were used in all cameras. Three cameras were used in the PAS group: Siemens Cios Alpha, Ziehm Vision RFD (RFD), and GE OEC 9900 Elite (GE9900). Three cameras were used in the MAS group: GE Advantx DLX, Philips Allura Xper FD20 (FD20), and Siemens Artis zee biplane. None of the systems were equipped with CT overlay functionality. Intraoperatively, transesophageal or transthoracic echocardiography (TTE) was performed adjunctively to guide fluoroscopic assessment of prosthesis implantation.

All patients received either a balloon-expandable (Edwards SAPIEN XT or SAPIEN 3, Edwards Lifesciences, Irvine, CA, USA) or self-expandable (Medtronic CoreValve Evolut, Medtronic, Minneapolis, MN, USA) prosthetic aortic valve, with a diameter of 23, 26, or 29 mm. The optimal valve type and size were selected based on patient specific anatomical and clinical factors.

Data collection and definitions

Baseline demographic and procedural characteristics were collected from the UHSH computerized health record. The STS risk score served as a proxy for coexisting medical conditions. Body mass index (BMI) was calculated using recorded height and weight. Baseline New York Heart Association (NYHA) heart failure class and left ventricular ejection fraction (LVEF)

Table 1. Patient demographics

Degree	Grade
None	0
Trace	I
Mild	II
Mild to Moderate	III
Moderate	IV
Severe	V

were defined from preoperative TAVR evaluation findings. Paravalvular leak (PVL) and postoperative LVEF ($LVEF_{1-day}$) reflect TTE findings on postoperative day 1. Using a previously described research-oriented PVL grading scheme [25], PVL was assigned a value according to Table 1. The 30-day LVEF ($LVEF_{30-day}$) was determined between 5 days and 3 months following TAVR. Postoperative NYHA class heart failure was defined by symptom burden at 30-day follow-up, which occurred between 21 days and 3 months following hospital discharge. When available, radiation exposure was quantified by dose area product (DAP), air kerma, and fluoroscopy time.

Definition of outcomes

Where appropriate, clinical outcomes were defined according to the Valve Academic Research Consortium-2 standardized definitions [26]. Mortality was assessed at 30 days and 1 year. All other outcomes were measured at 30 days, including ischemic stroke, life threatening or major bleeding, vascular complication requiring intervention, pacemaker implantation, and rehospitalization. Life threatening or major bleeding was defined using a packed red blood cell transfusion threshold ≥3 units during hospitalization, as previously described [26]. A vascular complication was noted to be any post-procedure access site intervention. The safety endpoint of excessive intraoperative radiation exposure was defined as a DAP greater than 1 standard deviation (SD) above the mean DAP for all patients (DAP > 13310 cGy*cm^2). The dichotomous composite safety outcome was defined as the occurrence of any of the above adverse events at 30 days, including excessive intraoperative radiation exposure or the presence of moderate or severe PVL.

Subgroups

Subgroup analysis was performed on selected demographic and procedural characteristics. Patients were categorized by BMI <20, 20 to <30, or ≥30 $\frac{\text{kg}}{m^{2}}$; STS risk score <3, 3 to 8, or >8%; and valve size implanted: small (23 mm Sapien XT/Sapien 3 or 23/26 mm CoreValve Evolut), medium (26 mm Sapien XT/Sapien 3 or 29 mm CoreValve Evolut), or large (29 mm Sapien XT/Sapien 3).

Statistical analysis

All statistical analysis was performed using SPSS software (25.0, SPSS Inc., Chicago, IL, USA). Normally distributed continuous variables were presented as mean ± SD, and compared using the two-tailed Student's t-test coupled with Levene's test for homogeneity of variance. Non-normally distributed continuous variables were presented as median (25th to 75th interquartile range), and were analyzed with the Mann-Whitney U test. Categorical variables were reported as frequency (%), and compared using the chi-square statistic, Fisher's exact test, or likelihood ratio, where appropriate. The Spearman's rank correlation coefficient was used in the univariate analysis of non-normally distributed continuous variables. Hazard ratios for the PAS group with two-sided 95% confidence intervals were generated using a Cox proportional-hazards model with the MAS group as the reference. In the subgroup analysis, hazard ratios were computed for the composite safety outcome of any adverse event at 30 days. Binary logistic regression was used to compute P-values for interaction between the subgroup variable and the composite safety outcome. Event free survival was compared between groups using the composite safety outcome of any adverse event at 30 days. Event free and cumulative survival curves were approximated using the Kaplan-Meier method, and event rates compared with the log-rank test. All tests were 2-sided, and a P-value <0.05 signified statistical significance.

Results

Baseline characteristics

Of the 101 TAVR cases reviewed, 24 patients were in the PAS group and 77 in the MAS group. Baseline characteristics were well balanced between groups

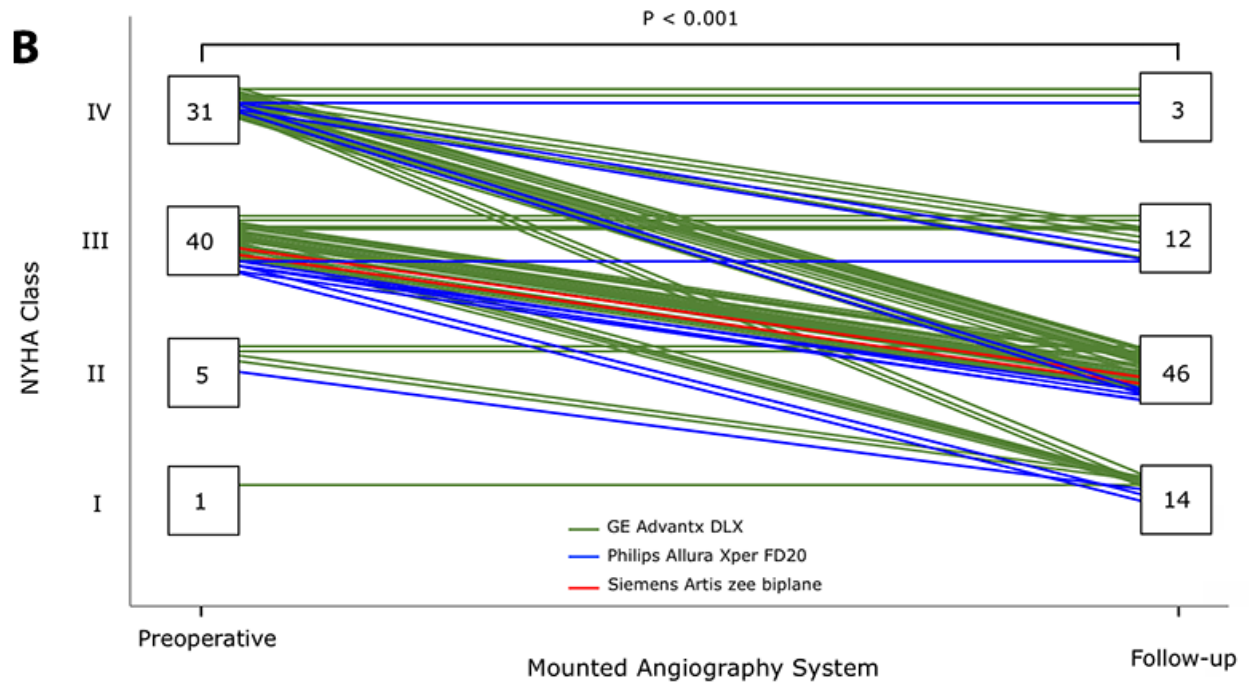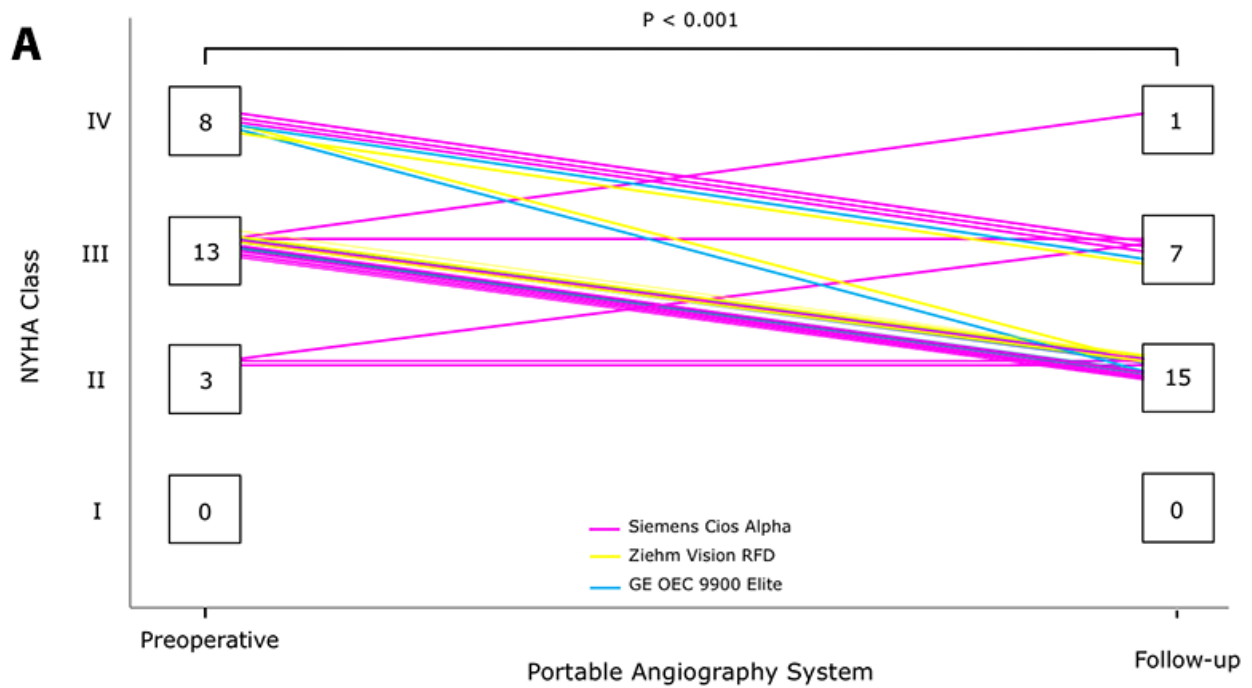**Figure 1.** Cardiac Symptom Status. Changes in New York Heart Association (NYHA) functional class heart failure according to intra-operative fluoroscopic camera used (*Panel A, PAS group; Panel B, MAS group*). Boxes contain number of patients in each NYHA class. Lines depict symptom trajectory for each patient from preoperative baseline to 30-day follow-up, which occurred between 21 days and 3 months following hospital discharge.

Table 2. Baseline Patient Characteristics.

Characteristic	Portable Angiography System (n = 24)	Mounted Angiography System (n = 77)	P Value
Age, yrs	81 ± 8	81 ± 8	0.78
Male sex	12 (50.0)	38 (49.4)	0.96
BMI	31 ± 8	29 ± 6	0.15
STS risk score, %	7.7 ± 4.6	7.8 ± 3.5	0.87
NYHA functional class			
I	0 (0.0)	1 (1.3)	0.67
II	3 (12.5)	5 (6.5)	
III	13 (54.2)	40 (51.9)	
IV	8 (33.3)	31 (40.3)	
LVEF, %	51 ± 11	53 ± 14	0.58

(Table 2). The mean STS risk score was 7.7% and 7.8% in the PAS and MAS group, respectively, indicating high risk cohorts. Patients in both groups exhibited predominantly NYHA class III or IV symptoms, with an overall similar distribution of baseline symptoms (P = 0.67). There was no significant difference in LVEF (PAS, 51% vs MAS, 53%, P = 0.58).

Procedural characteristics and outcomes

Procedural characteristics are provided in Table 3. The most commonly used camera in the PAS and MAS group was the Siemens Cios Alpha (70.8%) and the GE Advantx DLX (80.5%), respectively. While balloon expandable valves were more frequently employed in both groups, the overall distribution of valve types across groups was not significantly different (P = 0.053). Similarly, the distribution of the three valve sizes across groups was comparable (P = 0.95).

A majority of patients in the two study groups underwent TAVR using a transfemoral approach; however, a significantly greater proportion of patients in the PAS group underwent alternative vascular access (25.0% vs 1.3%, P = 0.001). No patient was converted from a transfemoral approach to an alternative vascular route. Similarly, no patient needed conversion to open surgical repair. The TAVR procedure was not aborted in any case.

The air kerma in the PAS group was significantly lower than in the MAS group (371 mGy vs 683 mGy, P = 0.043). Additionally, there was a non-significant trend towards lower DAP and fluoroscopy time in the PAS group compared to the MAS group (6566 $cGy*cm^2$ vs 9016 $cGy*cm^2$, P = 0.27; and 17 min vs 21 min, P = 0.16, respectively).

Clinical and echocardiographic outcomes

Clinical outcomes are summarized in Table 4. No significant differences were found in $LVEF_{1-day}$ or $LVEF_{30-day}$ in the PAS vs MAS group (54% vs 56%, P = 0.50; and 52% vs 53%, P = 0.80, respectively). Patients in each group experienced marked improvement in heart failure symptoms on follow-up (P < 0.001 in PAS and MAS group, Figure 1, Panel A and B). Rates of NYHA class III or IV symptoms on follow-up were similar between the two study groups (P = 0.17). All patients in the PAS group and a majority of patients in the MAS group had grade II or less PVL on postoperative day 1. As shown in Figure 2, no significant difference was observed in the distribution of PVL grades across groups (P = 0.22). The hospital and post-procedural length of stay were longer in the PAS group than in the MAS group (3 days vs 2 days, P = 0.005; and 3 days vs 2 days, P = 0.003, respectively).
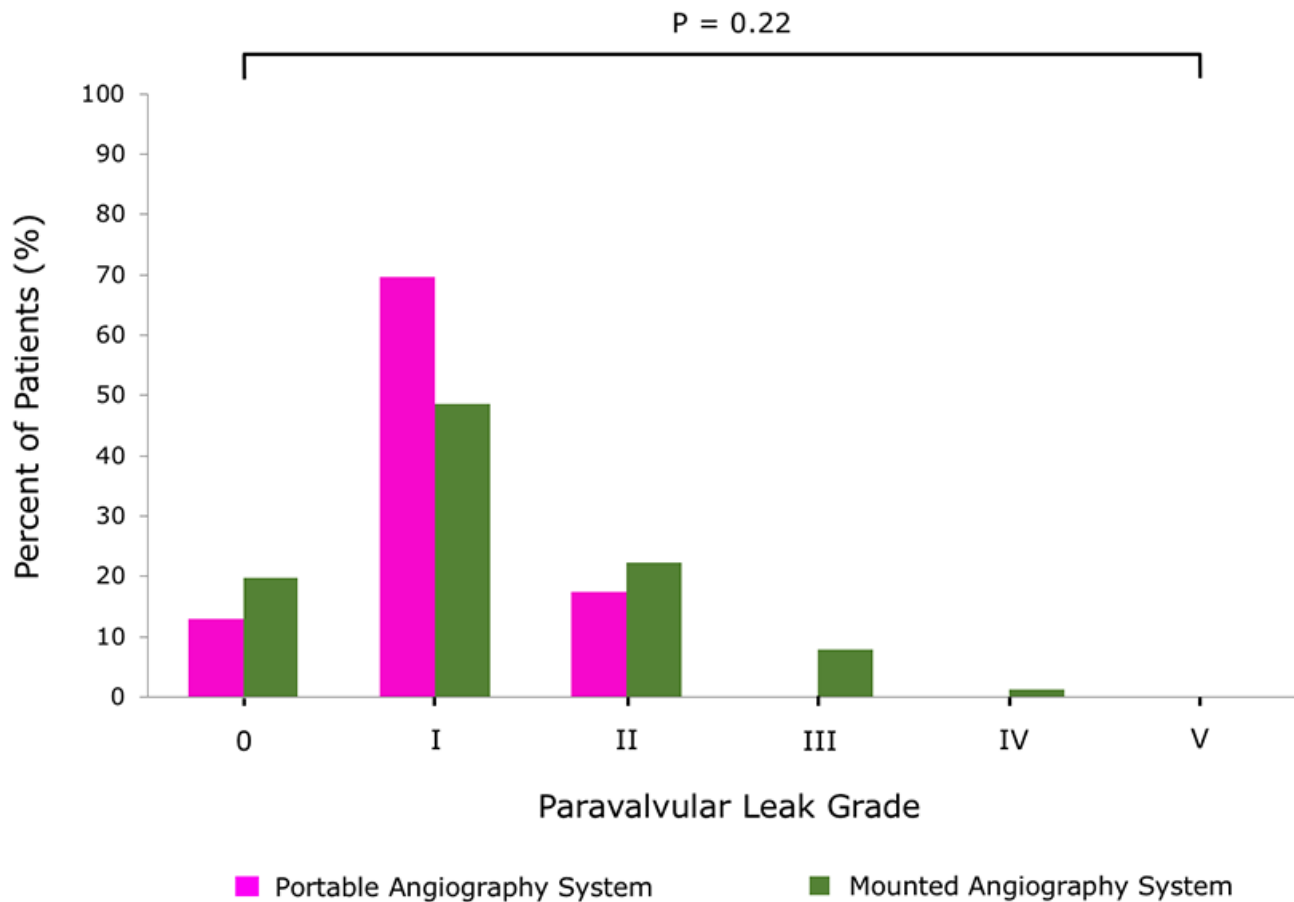
P = 0.22

Figure 2. Frequency of Paravalvular Leak (PVL) Grade. Comparison of PVL grade frequency between groups on postoperative day 1. Grading scheme as in Table 1.

Most 30-day adverse event rates were low and comparable in the PAS and MAS group. No between group differences were observed in all-cause mortality (PAS, 4.2% vs MAS, 2.6%, P = 0.56) or cardiovascular mortality (4.2% vs 1.3%, P = 0.42). Rates of ischemic stroke (P = 0.42), life threatening or major bleeding (P = 0.21), vascular complication requiring intervention (P = 0.62), pacemaker implantation (P = 0.39), and rehospitalization (P = 0.35) were all similar in each group.

The two groups did not differ significantly in the 1-year rates of all-cause (PAS, 21.7% vs MAS, 16.0%, P = 0.54) and cardiovascular mortality (4.3% vs 5.3%, P = 0.85). The Kaplan-Meier estimate of cumulative survival shows no significant difference in mortality between the PAS vs MAS group from 30-days to 1-year (hazard ratio [HR] for mortality with PAS vs MAS, 1.41;

95% confidence interval [CI], 0.50 to 4.01; log-rank P = 0.51; Figure 3, panel B).

The rate of the composite safety outcome of any adverse event at 30 days was similar in the PAS group compared to the MAS group (41.7% vs 33.8%, respectively), with no significant difference in the event free survival curves (HR for composite safety outcome with PAS vs MAS, 1.39; 95% CI, 0.67 to 2.88; log-rank P = 0.36; Figure 3, panel A). This finding was consistent across all three subgroups (Figure 4).

Discussion

This study demonstrates that in patients with severe symptomatic AS at high risk for open surgical repair, TAVR procedures can be performed using a new generation PAS with comparable safety and effi-

Table 3. Procedural Characteristics.

Characteristic	Portable Angiography System (n = 24)	Mounted Angiography System (n = 77)	P Value
Fluoroscopic camera			
Siemens Cios Alpha	17 (70.8)	-	
Ziehm Vision RFD	5 (20.8)	-	
GE OEC 9900 Elite	2 (8.3)	-	
GE Advantx DLX	-	62 (80.5)	-
Philips Allura Xper FD20	-	13 (16.9)	
Siemens Artis zee biplane	-	2 (2.6)	
Valve type			
Sapien XT	4 (16.7)	33 (42.9)	
Sapien 3	14 (58.3)	34 (44.2)	0.053
CoreValve Evolut	6 (25.0)	10 (13.0)	
Valve size, mm			
23	9 (37.5)	27 (35.1)	
26	7 (29.2)	25 (32.5)	0.95
29	8 (33.3)	25 (32.5)	
Alternative vascular access			
Transaortic	1 (4.2)	0 (0.0)	
Transapical	4 (16.7)	0 (0.0)	0.001
Transsubclavian	1 (4.2)	1 (1.3)	
Radiation dose			
DAP, cGy*cm^2	6566 ± 3335	9016 ± 7745	0.27
Air kerma, mGy	371 ± 145	683 ± 534	0.043
Excessive radiation exposure ★	1 (5.0)	4 (26.7)	0.14
Fluoroscopy time, min	17 ± 7	21 ± 13	0.16

Values are number (%) and mean ± SD.
★ Defined as DAP > 13310 cGy*cm^2.
DAP = dose area product.

cacy to a traditional MAS. We observed no statistically significant differences in rates of mortality, ischemic stroke, life threatening or major bleeding, vascular complication requiring intervention, pacemaker implantation, or rehospitalization. Additionally, both groups had similar improvement in NYHA class symptoms and degree of PVL. For the composite safety outcome of any adverse event at 30 days and for mortality at 1 year, the two study groups had comparable event-free survival. As a result of these findings, we believe PAS can be used as an alternative to MAS during TAVR.

Overall, the features of new generation PAS fluoroscopic systems compare well to those of MAS systems, which may explain, in part, why the two study groups experienced similar clinical outcomes. The specifications of the PAS cameras and the newest MAS camera used in this study (the FD20) are compared in Table 5.

All three PAS cameras offer radiation dose monitoring and reduction features comparable to the FD20 ClarityIQ, Doseaware, SpectraBeam, and MRC-GS 0407 technologies [27-29]. Like the FD20, the GE9900 and RFD cameras offer high frequency X-ray generators, while the Cios Alpha generator uses a monoblock de-
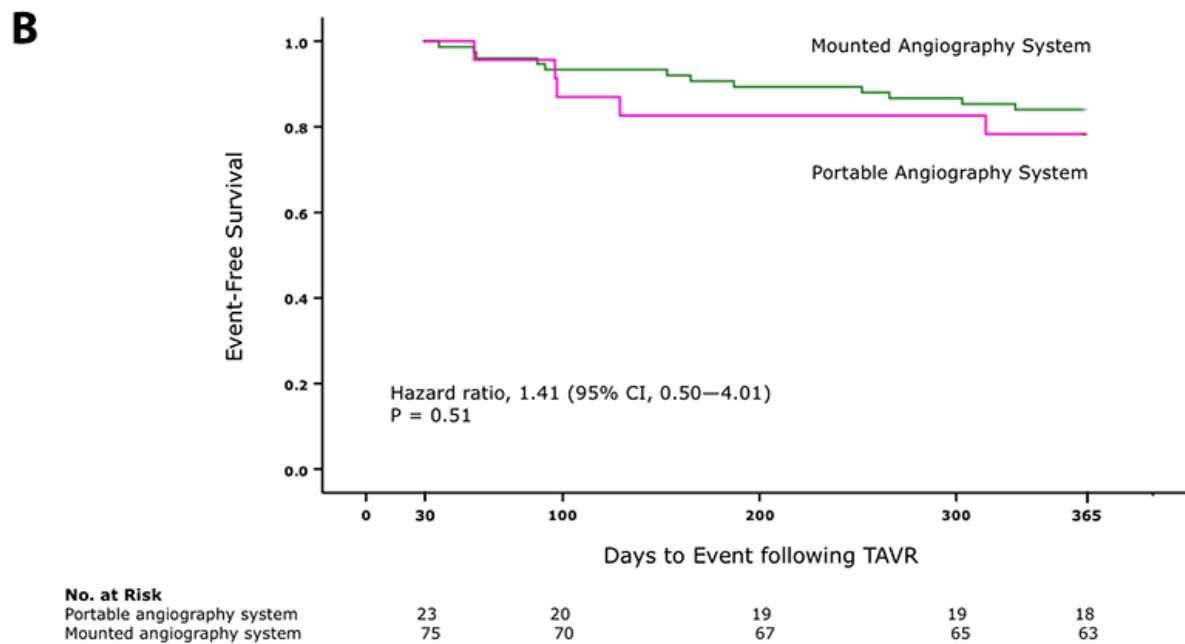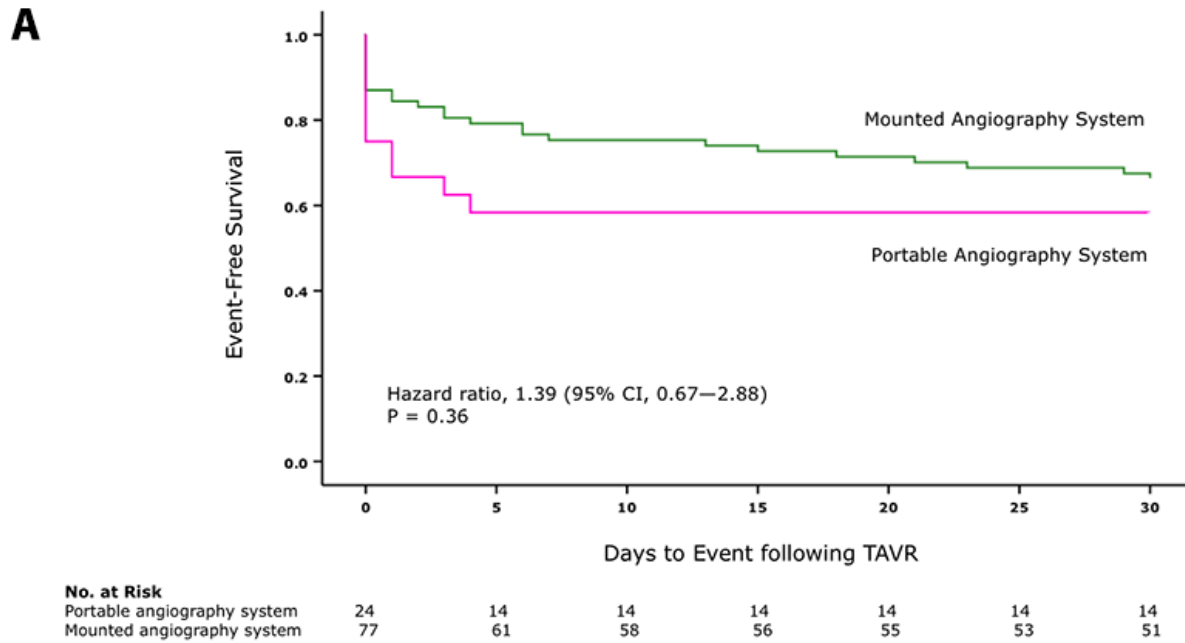
Figure 3. Survival Curves for the Composite Safety Outcome of Any Adverse Event at 30 Days, and All-Cause Mortality from 30-Days to 1-Year. Event-free survival curves for the composite safety outcome of any adverse event (mortality, ischemic stroke, life threatening or major bleeding, vascular complication requiring intervention, pacemaker implantation, rehospitalization, excessive intraoperative radiation exposure, or moderate or severe paravalvular leak) at 30 days *(Panel A)*. The number of patients in each group surviving without an event at each 5-day interval is shown. Cumulative survival curves from day 30 to 1 year *(Panel B)*. The number of patients in each group surviving at each interval (varies) is shown. Event rates were calculated using the Kaplan-Meier estimate and compared using the log-rank test.

Table 4. Outcomes.

Outcome	Portable Angiography System (n = 24)	Mounted Angiography System (n = 77)	P Value
$LVEF_{1-day}$, %	54 ± 12	56 ± 13	0.50
$LVEF_{30-day}$, %	52 ± 11	53 ± 12	0.80
NYHA functional class III or IV ★	8 (34.8)	15 (20.0)	0.17
Grade PVL†			
0	3 (13.0)	15 (19.7)	
I	16 (69.6)	37 (48.7)	
II	4 (17.4)	17 (22.4)	0.22
III	0 (0.0)	6 (7.9)	
IV	0 (0.0)	1 (1.3)	
V	0 (0.0)	0 (0.0)	
Length of stay, days ‡	3 (2-7)	2 (1-3)	0.005
Length of stay: procedure to discharge, days ‡	3 (2-4)	2 (1-2)	0.003
30 Days			
Mortality			
All-cause	1 (4.2)	2 (2.6)	0.56
Cardiovascular cause	1 (4.2)	1 (1.3)	0.42
Ischemic stroke	1 (4.3)	1 (1.3)	0.42
Life threatening or major bleeding	4 (16.7)	5 (6.6)	0.21
Vascular complication requiring intervention	2 (8.7)	4 (5.3)	0.62
Pacemaker	3 (13.0)	5 (6.7)	0.39
Rehospitalization	2 (8.7)	14 (18.7)	0.35
1 Year			
Mortality			
All-cause	5 (21.7)	12 (16.0)	0.54
Cardiovascular cause	1 (4.3)	4 (5.3)	0.85

Values are number (%), mean ± SD, and median (25th-75th percentile) for non-normally distributed variables.
★NYHA class symptoms at 30-day follow-up, which occurred between 21 days and 3 months following hospital discharge.
†Grading scheme as in Table 1.
‡Non-normally distributed variable.
LVEF1-day = LVEF on postoperative day 1; LVEF30-day = LVEF determined between 5 days and 3 months post-TAVR; PVL = paravalvular leak on postoperative day 1; other abbreviations as in Table 2.

sign. The PAS and FD20 cameras are all equipped with a pulsed fluoroscopy mode, which generally ranges from 1 to 30 fps, though the FD20 is capable of 60 fps. The contemporary PAS systems (Cios Alpha and RFD) offer fluoroscopic mA ranges similar to that of the FD20, and have housing heat storage capacities of 5.3 MHU and 10 MHU, respectively, which are similar to the FD20 capacity of 5.4 MHU. The comparable heat capacity of PAS cameras in conjunction with their liquid cooling technology reduce the risk of sys-
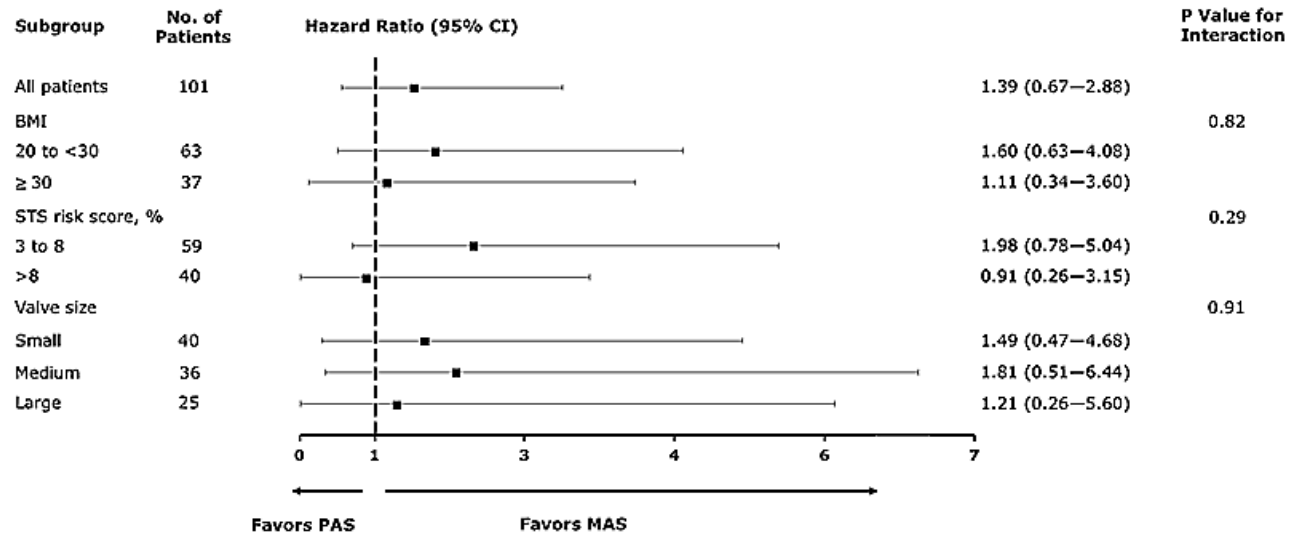
Subgroup	No. of Patients	Hazard Ratio (95% CI)		P Value for Interaction
All patients	101		1.39 (0.67—2.88)	
BMI				0.82
20 to <30	63		1.60 (0.63—4.08)	
≥ 30	37		1.11 (0.34—3.60)	
STS risk score, %				0.29
3 to 8	59		1.98 (0.78—5.04)	
>8	40		0.91 (0.26—3.15)	
Valve size				0.91
Small	40		1.49 (0.47—4.68)	
Medium	36		1.81 (0.51—6.44)	
Large	25		1.21 (0.26—5.60)	

Favors PAS   Favors MAS

Figure 4. Subgroup Analysis for the Composite Safety Outcome of Any Adverse Event at 30 Days. Subgroup analysis for the composite safety outcome (defined as in Figure 3) at 30 days. Hazard ratios were generated using the Cox-proportional hazards model with the MAS group as the reference. Data markers indicate mean hazard ratios; lines represent 95% confidence interval. P values represent the likelihood of interaction between the subgroup variable and the composite safety outcome. Abbreviations as in Table 2. Valve size: small = 23 mm Sapien XT/Sapien 3 or 23/26 mm CoreValve Evolut; medium = 26 mm Sapien XT/Sapien 3 or 29 mm CoreValve Evolut; large = 29 mm Sapien XT/Sapien 3.

tem overheating, which is particularly advantageous during prolonged procedures.

The PAS cameras have power ratings ranging from 15 to 25 kW at 100 kVp, compared to the 100 kW at 100 kVp power rating of the FD20 [27-29]. Our analysis suggests that the increased power rating of the FD20 does not confer a procedural advantage during TAVR, and may in fact contribute toward higher radiation doses. In addition, the contemporary PAS cameras utilize a digital flat panel display, which is also employed by the FD20. Compared with image intensifiers, flat panels have the advantage of minimizing image distortion [30]. However, the PAS flat panel detectors are smaller than that of the FD20, which may additionally explain why the PAS group experienced less radiation.

The PAS group had a significantly longer hospital length of stay compared to the MAS group. Univariate analysis demonstrated a significant association between length of stay and alternative vascular access use (P = 0.004). Since the PAS group underwent significantly more alternative access, it is not unexpected then that they experienced a longer hospital stay.

Another important finding of this study was the trend toward lower radiation exposure in the PAS group. This likely represents a fundamental difference between PAS and MAS systems, whereby owing to their higher power rating and larger imaging field of view, MAS cameras accrue greater radiation doses, even when equivalent pulsed fluoroscopy settings are applied. This benefit of PAS over MAS appears to hold independently of fluoroscopy time, which was not significantly different between groups. Interestingly, the radiation doses observed in both the PAS and MAS group are lower than those reported in two prior studies investigating radiation exposure during TAVR [31, 32]. This discrepancy is largely attributed to lower fluoroscopy times used in our study, which reflect simplifications in TAVR procedure complexity over time.

While MAS remains the mainstay of intraoperative fluoroscopic imaging during TAVR procedures, PAS offers unique advantages. PAS cameras are versatile platforms which can complement existing MAS cameras, expanding the imaging armamentarium of institutions participating in complex fluoroscopy-guided subspecialty procedures (Figure 5). Furthermore, PAS

Table 5. Comparison of Camera Characteristics ★

	PAS			MAS
Product name	Siemens Cios Alpha	Ziehm Vision RFD	GE OEC 9900 Elite	Philips Allura Xper FD20
FDA cleared, yr	2014	2009	2008	2013
Type	Mobile C-arm	Mobile C-arm	Mobile C-Arm	Ceiling mounted single plane
Radiation lowering/dose control features	Yes	Pulsed fluoroscopy; low-dose mode; object detected dose control; PreMag; removable grid	Pulsed fluoroscopy; low-dose mode; preview collimator; laser aimer	ClarityIQ
Radiation dose monitoring features (for staff and/or patients)	Yes	Calculated DAP; air kerma; measured DAP (option); structured dose report	Yes	DoseAware
X ray generator Type	Monoblock	Monoblock and high frequency	High frequency split block	High frequency
Power rating, kW at 100 kVp	25	20 / 25	15	100
Radiographic mA	10 - 250	Up to 20	Up to 75	1 - 1250
Radiographic kV	40 - 125	40 - 110	50 - 120	40 - 125
Fluoroscopic mA	3 - 250	1.5 - 180 (at 20 kW); 1.5 - 250 (at 25 kW)	Normal: 0.2 - 10; HLF: 1 - 20	60
Fluoroscopic kV	40 - 125	40 - 120	40 - 120	40 - 125
Focal spot size (mm)	0.3	Dual focus: 0.3 / 0.6	0.3 - 0.6	0.4 and 0.7 (MRC)
Pulsed fluoroscopy; Cine range (fps)	Yes; 0.5 - 30	Yes; 1, 2, 4, 8, 15, 30; Cine 1 - 25	Yes; 1, 2, 4, 8, 15; up to 30 fps	Yes; 3.25, 7.5, 15 and 30 fps; optional 60 fps
Housing heat storage capacity, MHU	5.3	Anode: 0.365; System: 10	0.3	Anode: 2.4; System: 5.4
Diameter of intensifier or dimensions of detector, cm	30x30; Cardiac 20x20	30x30 (a-Si); 20x20	31x23x15 image intensifier	30x38

★ Adapted from references 27-29.
kVp = peak kilovoltage; HLF = high level fluoro; a-Si = amorphous silicon; other abbreviations as in Table 3.

can simplify operative workflow, condense OR space allocation, and reduce resource consumption, all of which have the potential to reduce overall cost. PAS may also be used to facilitate conversion of a traditional OR to a hybrid OR, reducing the transition time for implementing a TAVR program. As TAVR procedures become more routinely performed in lower risk populations, PAS allows institutions seeking to initiate or expand TAVR programs to do so without further straining institutional resources.

Our study is limited by small sample size and single center, retrospective design. Though the same imaging mode was used in both fluoroscopic camera systems, there may have been differences in their calibrations, which could confound the observed differences in outcomes. Furthermore, the relatively small sample size increases the risk of a type II error. The limitation of sample size is further demonstrated in radiation measurements. Because the GE Advantx DLX camera did not monitor radiation exposure, there may have been insufficient power to detect a statistically significant difference in DAP. Similarly, while the subgroup analysis was consistent with the overall observations of the study, there may have been insufficient power to detect a statistically significant interaction be-
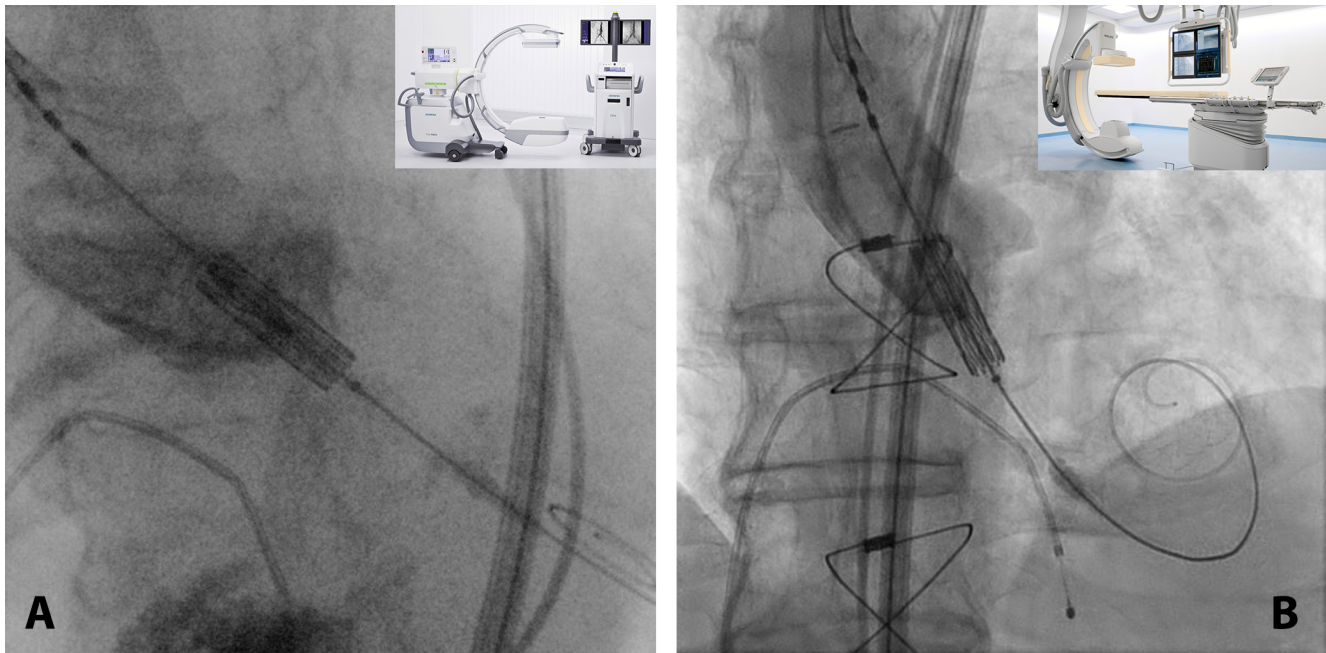
Figure 5. Aortic root angiogram confirming prosthesis positioning predeployment. Siemens Cios Alpha, PAS *(Panel A)*. Philips Allura Xper FD20, MAS *(Panel B)*. Inset, corresponding fluoroscopic camera.

tween subgroups and the composite safety outcome of any adverse event at 30 days.

In conclusion, our study demonstrates that PAS is a safe and effective imaging modality for TAVR procedures with less total radiation exposure than MAS. Future prospective studies with larger sample sizes are needed to clarify this finding.

Acknowledgement

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

<div style="border:1px solid blue; text-align:center;">**Comment on this Article or Ask a Question**</div>

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Diagnosis and Management of Fontan Failure Secondary to Aortopulmonary Artery Fistula

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Abstract

Aortopulmonary artery fistula represents a rare anomalous communication between aorta and pulmonary artery. The treatment of these communications is well established and involves either surgical or percutaneous approach. We present a 15-year-old male with history of hypoplastic left ventricle, hypoplastic aorta and ventricular septal defect with Damus-Kaye-Stansel surgery in the past, who developed acute Fontan circuit failure secondary to the development of aortopulmonary fistula of unknown etiology. Fistula was successfully closed percutaneously, using Amplatzer duct occluder.

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Key Words

Aortopulmonary artery fistula • Congenital heart disease • Duct occluder
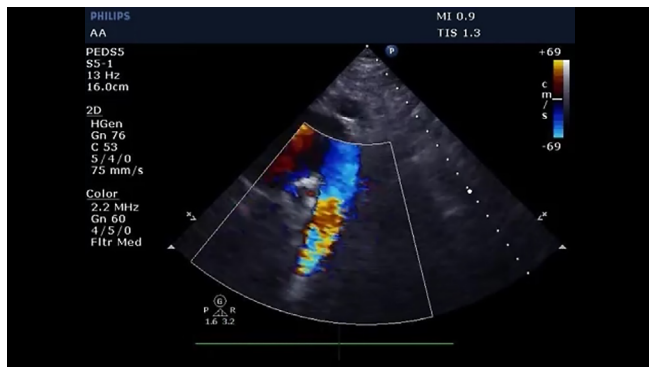
Introduction

Aortopulmonary artery fistula (APF) represents an anomalous communication between aorta and pulmonary artery. It is a rare occurrence. There are two types of APFs described in the literature: congenital and acquired. Congenital APFs are extremely rare and have only been described in case reports [1]. On the other hand, acquired APFs are relatively more common and usually associated with pseudo-aneurysm that breaks into the pulmonary artery [2-4]. They may or may not be associated with trauma [5]. Treatment for these abnormal communications is well established and is either surgical or percutaneous [2, 6]. We present an interesting case of Fontan circuit failure due to development of aortopulmonary artery fistula in a 15-year-old male with history of complex congenital heart disease including hypoplastic left ventricle, hypoplastic aorta and ventricular septal defect (VSD) with Damus-Kaye-Stansel surgery in the past followed by Fontan palliation with fenestration and transcatheter fenestration closure years after primary surgery. He presented to emergency department with increasing abdominal pain in the setting of recent bicycle accident followed by dyspnea on exertion.

Case presentation

15-year-old male with history of complex congenital heart disease, status post Fontan palliation presented to an outside hospital (OSH) ER two weeks after a fall while riding his bike when flipped over the handle bars. Over the two-week period following the accident, patient developed increasing abdominal discomfort and dyspnea on exertion and finally pre-

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Video 1. The reversal of flow in descending aorta in diastole without aortic regurgitation. View supplemental video at https://doi.org/10.12945/j.jshd.2019.014.18.vid.01.
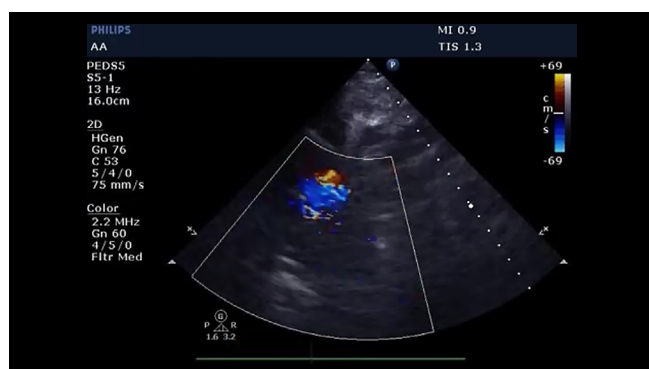
Video 2. Shunt-like flow coming from aorta to pulmonary artery (transthoracic echocardiogram). View supplemental video at https://doi.org/10.12945/j.jshd.2019.014.18.vid.02.
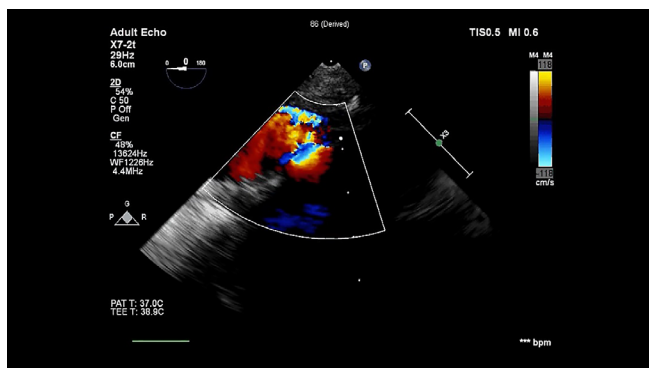
Video 3. APF between the posterior right aspect of the aorta and the pulmonary artery (transesophageal echocardiogram). View supplemental video at https://doi.org/10.12945/j.jshd.2019.014.18.vid.03.

sented to ER due to severe abdominal pain, mostly localized to right upper quadrant.

At the OSH ER abdominal CT was done which showed questionable injury to liver and spleen. At that moment it was decided to transfer the patient to our hospital for trauma evaluation. Following arrival to our hospital, abdominal CT was found to be reassuring. Upon further questioning it came to our knowledge that patient had multiple months of increased exercise intolerance including dyspnea on exertion which was occurring quicker into activities. Patient also reported orthopnea and was using an extra pillow to sleep during this time. Given the afore mentioned, chest X-ray was obtained and found to be concerning for bilateral pleural effusions.

Cardiology was consulted due to positive history of complex congenital heart disease. Transthoracic echocardiogram (TTE) was completed and showed reversal of flow in descending aorta in diastole without evidence of aortic regurgitation (Video 1). Further investigation on echocardiogram made us suspect that there is shunt-like flow coming from aorta to pulmonary artery (Video 2), but it was not clearly identified on TTE. It was determined that a diagnostic catheterization and transesophageal echocardiography (TEE) would be needed to identify the source.

The patient had increased oxygen requirements due to worsening pleural effusions and increasing ascites requiring transfer to the cardiac intensive care unit where bilateral thoracentesis was performed. Bilateral 8 Fr chest tubes were placed followed by almost complete resolution of his bilateral pleural effusions. However, prior to catheterization the patient had a persistent right sided pleural effusion causing desaturations while under anesthesia. Right chest tube (20 Fr) was placed which helped stabilize the patient but failed to adequately drain the effusion. The patient was taken to the catheterization lab where surgical drainage was performed under general anesthesia.

Once placed under anesthesia and the right sided pleural effusion drained, TEE was done. The TEE confirmed our suspicion of APF between the posterior right aspect of the aorta and the pulmonary artery (Video 3). It was determined that a percutaneous approach should be attempted with cardiothoracic surgery back up.

Right heart catheterization was performed using 7-Franch Berman angiographic catheter and revealed
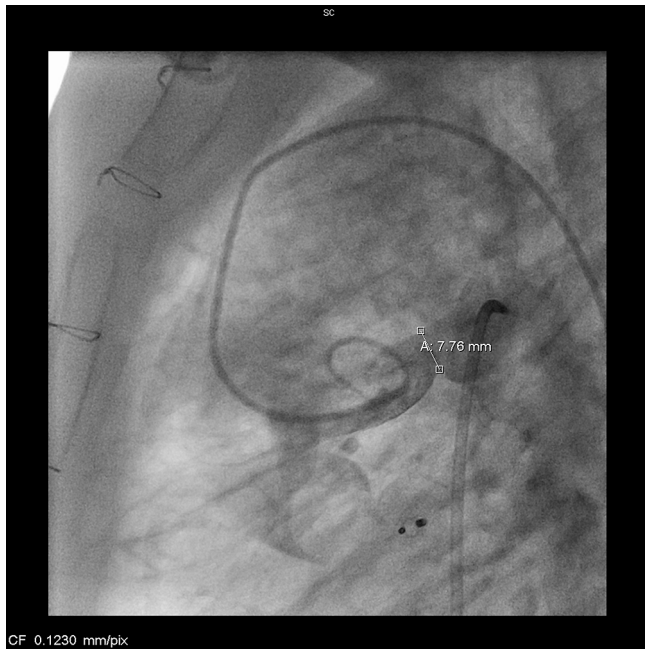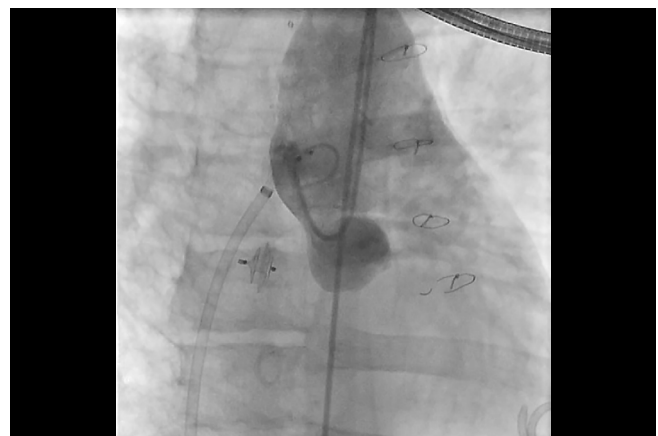
Figure 1. APF diameter measuring 7 mm.

inferior vena cava, superior vena cava, Fontan baffle and pulmonary artery pressures to be all at a mean of 25 mm Hg implying increased pressure in Fontan circuit without obstruction. Pulmonary angiogram also showed contrast washout in pulmonary artery suggesting additional flow coming from high pressure setting (Video 4). Retrograde left heart catheterization performed with 6-French pigtail catheter revealed left ventricular pressure of 90/10 mmHg and no gradient to the ascending or descending aorta where pressure was 90/35 mmHg. An aortogram was performed in postero-anterior and lateral projections demonstrating competent aortic and neo-aortic valve and normal coronary flow. Angiogram confirmed presence of aortopulmonary artery fistula (Video 5). The diameter of fistula was measured to be 7 mm (Figure 1) prior to advancing balloon sizing catheter. After creating arteriovenous loop, a balloon sizing catheter was advanced from the venous side and softly inflated across the fistula. The decision was made to close the fistula using Amplatzer duct occluder 10/8 mm in size. After successful positioning of the device and its release, a post-release aortogram confirmed good position and a trivial residual shunting through the device which was expected (Video 6). Post-release TEE also confirmed the device to be in a
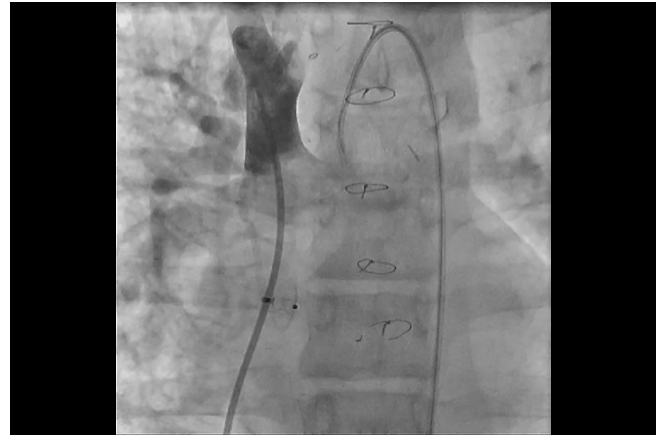
Video 4. Contrast washout in pulmonary artery suggesting additional flow coming from high pressure setting (pulmonary angiogram). View supplemental video at https://doi.org/10.12945/j.jshd.2019.014.18.vid.04.
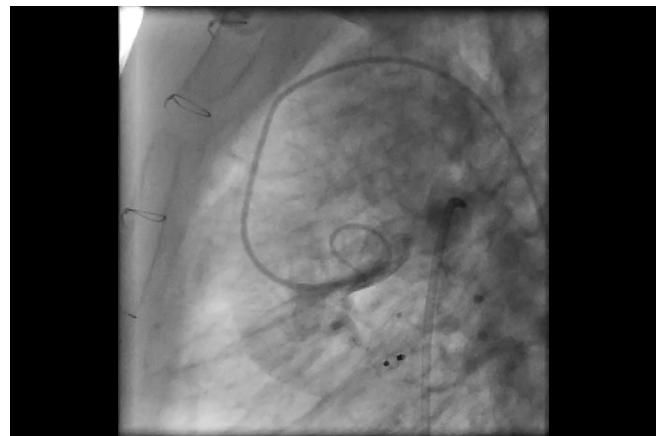
Video 5. Aortopulmonary artery fistula. View supplemental video at https://doi.org/10.12945/j.jshd.2019.014.18.vid.05.

Video 6. Device position with trivial residual shunting. View supplemental video at https://doi.org/10.12945/j.jshd.2019.014.18.vid.06.

good position. Following the closure of the fistula, the Fontan circuit pressure decreased from 25 mm Hg to 20 mm Hg of mean pressure.

The patient was extubated in catheterization lab and transferred back to the intensive care unit. Over the next couple of days, the patient improved and both chest tubes were removed. TTE prior to discharge showed a small shunt at the site of the fistula, but overall improved. Patient was discharged home with cardiology follow-up and twice daily Furosemide with plan to wean the medication over the next few weeks. Outpatient cardiology follow-up showed consistent improvement.

Discussion

Aortopulmonary artery fistula is a rare type of anomalous vascular communication. This unusual communication, reportedly, has been associated to aortic aneurysm or has appeared as a complication of aortic aneurysm rupturing into the pulmonary artery [2].

There are two types of APF: congenital and acquired. Congenital AFP are extremely rare but have been described in case reports in which patients also had an associated coronary artery fistula. The pathogenesis is not very well understood. [1]

Our case likely represents a case of acquired APF given that this is a patient with history of complex congenital heart disease who had multiple echocardiographic evaluations and catheterizations in the past not revealing the anomalous communication. However, the etiology is still not clear. It has been shown that aortopulmonary collateral vessels occur with the overall prevalence of 36% in the population of patients who have undergone bidirectional Glenn or Fontan procedure [7] , a category under which our patient falls.

Acquired APF in the pediatric and adult populations are shown to be associated with some level of defect in the wall of the great vessels including an intimal tear, pseudoaneurysm or aneurysm breaking into the pulmonary artery and resulting in direct communication between these great vessels [3, 4]. In pediatric populations, there have been multiple reports of iatrogenic APF formations after pulmonary angioplasty using different devices for percutaneous closure [8, 9]. In all cases, a mild intimal tear in

the pulmonary artery or its branches was revealed using magnetic resonance imaging (MRI). Trauma is a significant risk factor for the development of mild to severe injuries of the vessel wall that can lead to fistula formation [4, 5]. Most vessel wall injuries, even minor ones, would likely be seen on MRI which was not done in this case. However, it is reasonable to say that his bicycle accident could have predisposed him to developing a minor tear in the wall of his great vessel. Although our patient did have a fall prior to presentation, his symptoms date back prior to the fall, therefore the etiology of his condition remains uncertain.

APF leads to significant left-to-right shunt and places a hemodynamic burden on the heart and lungs. Clinical presentation is consistent with variable level of congestive heart failure depending on the diameter of the anomalous vessel as well as the predisposing factors such as trauma. In case of significant left-to-right shunting from aorta to pulmonary artery, as described in our patient with APF where blood was shunted from aorta where systolic pressure was 90 mmHg to a much lower pressure in pulmonary artery leading to increased Fontan circuit pressures to 25 mm Hg and overcirculation of the pulmonary vascular bed with consequent dyspnea, pleural effusions and pulmonary edema. Additionally, increased Fontan circuit pressure leads to liver congestion, ascites and abdominal symptoms. In patients with Fontan palliation, in order for the circuit to function properly, low circuit pressures must be maintained. The increase in Fontan circuit pressure to 25 mm Hg in our patient contributed significantly to liver congestion and to ascites formation further on. It is well known that high venous pressures can compromise lymphatic circulation as well. Additionally, the extension of Glisson's capsule can also lead to right upper quadrant abdominal pain that our patient initially presented with.

The treatment of APF includes surgical repair or percutaneous closure of the anomalous vessel using different types of devices. Surgical treatment is the treatment of choice in the case of aortic pseudoaneurysm or aneurysm rupturing into the pulmonary artery and in case of severe trauma leading to the communication of the great vessels. Percutaneous embolization has become the treatment of choice for the occlusion of anomalous arteriovenous and

veno-venous connections frequently seen in patients with congenital heart disease [10]. Major advantages of transcatheter closure are the decreased need for reoperation leading to decreased postoperative morbidity and mortality [11]. APF occlusion using Amplatzer vascular occluder, in our patient, lead to a decrease in Fontan circuit pressures to a mean pressure of 20 mm Hg while the patient was still intubated and on positive pressure ventilation and it was expected for this pressure to decrease further with resolution of pleural effusions and ascites, as it was observed. Today, many devices are available for percutaneous closure of APF including coils, plugs, microspheres, glue and occlusion balloons and its safety and efficacy has been well established so far [6, 8, 10, 11].

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Acknowledgement

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

Patent Foramen Ovale Closure using Cardioform Occluder Device Through the Right Internal Jugular Vein for Primary Prevention (First in Man): Importance of a Multidisciplinary Team

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Abstract

Percutaneous transcatheter closure of Patent Foramen Ovale (PFO) is usually performed via the femoral vein but in certain circumstances this approach may not be possible necessitating the need for an alternative access. The right internal jugular vein has been successfully utilized in these cases. We are presenting the first successful PFO closure using a Cardioform Occluder Device to close a PFO as a primary prevention approach in a patient with a large inferior vena cava thrombus from renal cell carcinoma.

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Key Words

PFO • Peri-operative risk • IVC thrombus • Cardioform device • Right internal jugular vein • Primary prevention • Multidisciplinary approach

Introduction

Transcatheter closure of patent foramen ovale (PFO) is a standard and growing procedure at many health care centers. Recently, three promising randomized clinical trials: CLOSE [1], Gore REDUCE [2] and RESPECT [3]; and an updated meta-analysis [4] support PFO closure in patients with cryptogenic stroke compared to medical therapy advocating for an update to the current guidelines. In addition, there are still no primary prevention recommendations for PFO closure. The procedure is usually easily performed with a trans-femoral venous approach given the anatomy of the inferior vena cava (IVC) and the interatrial septum (IAS). However, certain conditions such as an IVC thrombus as in our case may preclude using this access, hence the need for alternative approach such as via the right internal jugular vein (R-IJ).

PFO closure using the R-IJ vein has been successfully reported in several case reports using different occluder devices such as a 25-mm Multi-fenestrated ASD occluder [5] and a Figula Flex II PFO 23/25 mm occluder device [6].

We present the first case to the best of our knowledge of closing a PFO using a 30mm Cardioform Occluder Device (COD) from the R-IJ vein in a patient without a history of stroke with an IVC thrombus from renal cell carcinoma (RCC).

Patients with RCC and IVC tumor related thrombus have poor prognosis and radical nephrectomy with thrombectomy is considered to be potentially curative [6]. In our case, the patient had a PFO (Figure 1) and symptomatic severe AS that increased her surgical risk of major adverse cardiovascular events and death.

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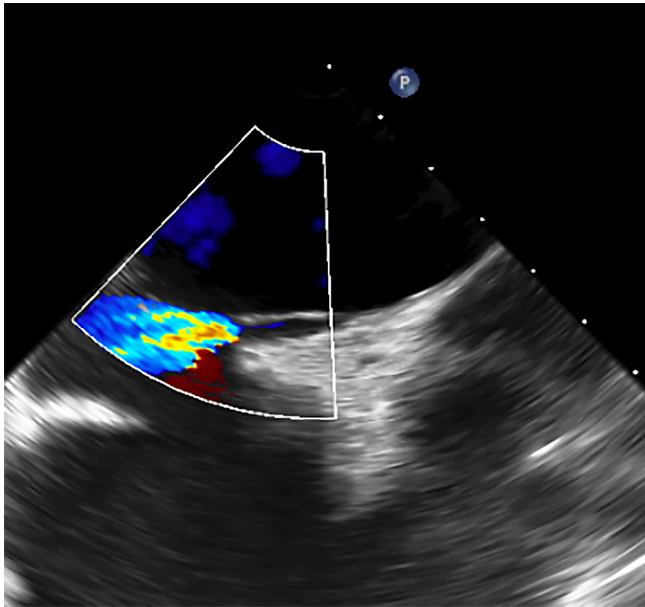
Figure 1. Transesophageal Echocardiogram of the patent foramen ovale with color doppler.

Case presentation

A 65-year-old woman with stage T3bN1M0 RCC was seen in the structural cardiology clinic as a consultation regarding the management of her PFO and severe AS before the surgical resection of the recently discovered left RCC with an extensive IVC tumor-related thrombus (Figure 2). Due to the high intraoperative risk of clot embolization causing a stroke via the PFO and the high surgical risk given her severe AS, it was decided to proceed with PFO closure and aortic valve replacement (AVR) before her radical nephrectomy. She was evaluated by our heart team and deemed high risk for surgical AVR, hence Transcatheter Aortic Valve Replacement (TAVR) was recommended for the treatment of her aortic stenosis.

The procedure

R-IJ vein approach PFO Closure using 30 mm Cardioform Occluder Device

General anesthesia was utilized in this procedure due to the need for transesophageal echocardiography (TEE). A 6Fr sheath was inserted into the RIJ and hemodynamic measurement was obtained showing the following hemodynamics: Right atrial (RA) pressure=12mmHg, systolic pulmonary artery pressure=33mmHg with a mean of 24mmHg, post-capillary wedge pressure=17mmHg, estimated cardiac
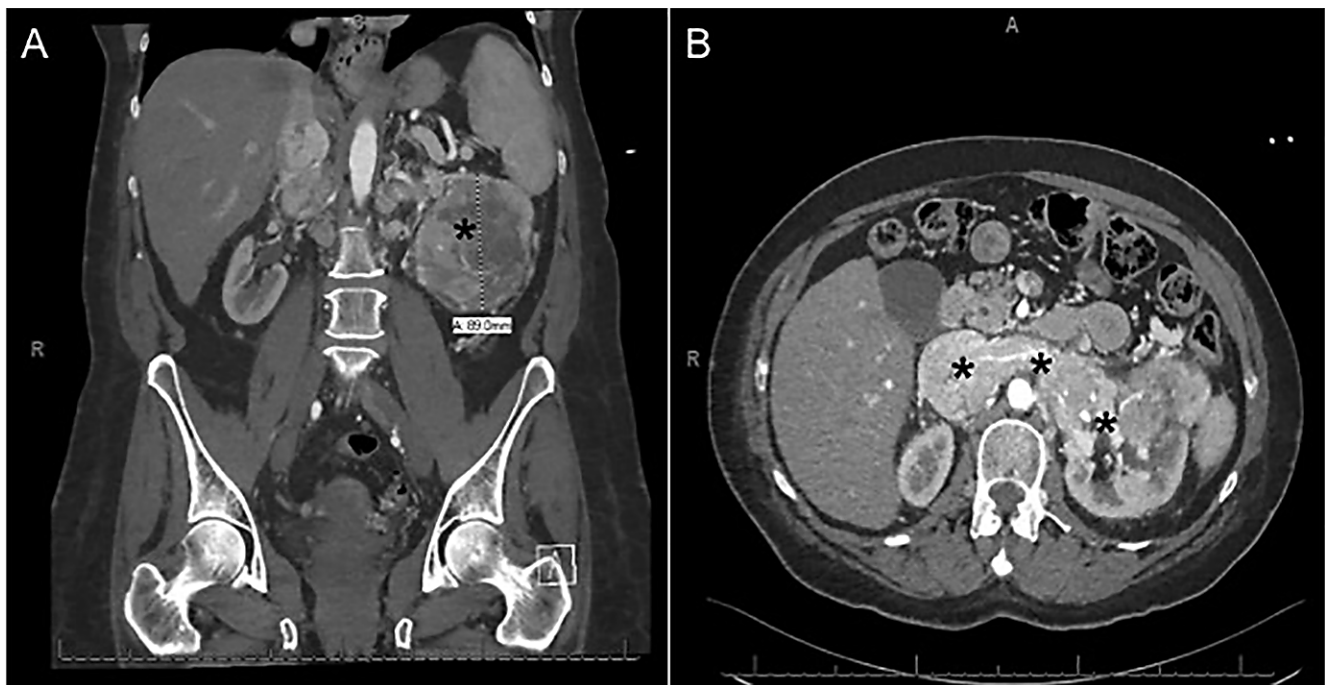

Figure 2. Computerized tomography images of the left renal mass *(Panel A)* and thrombus *(Panel B)* extending through the left renal vein into the inferior vena cava (IVC). *: Indicates the renal mass and thrombus extending into the IVC.
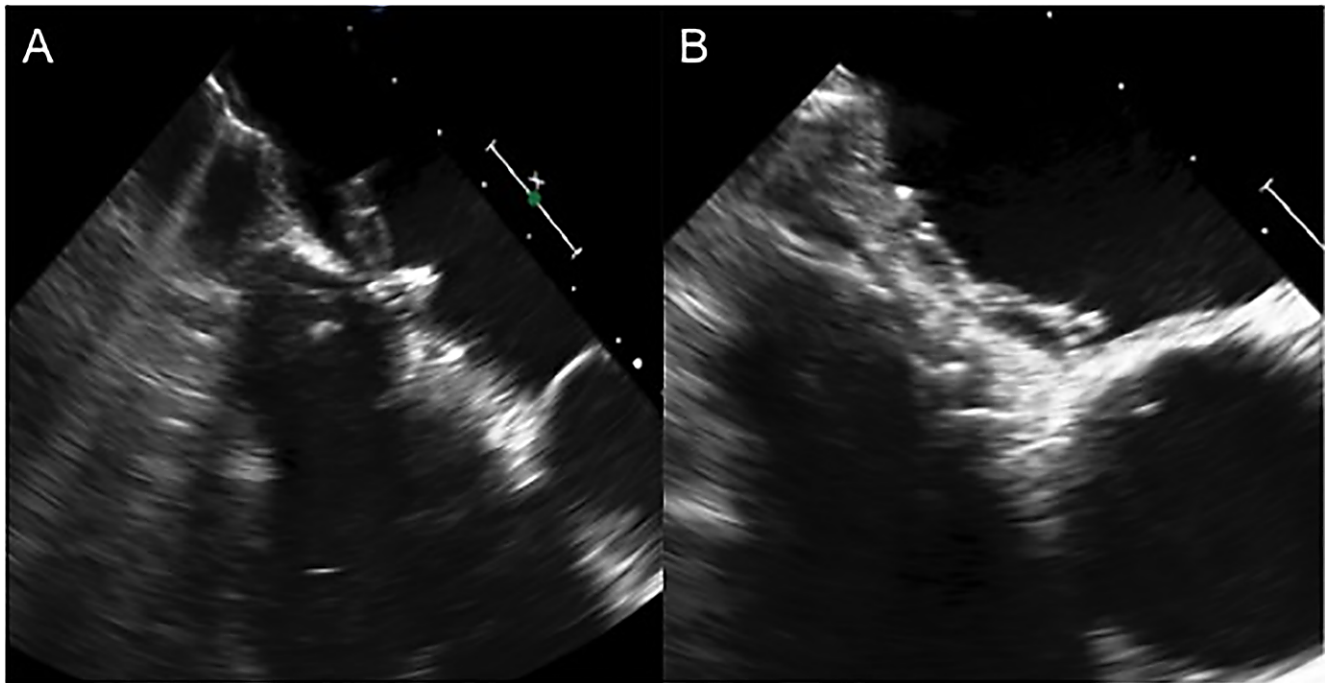
Figure 3. Transesophageal echocardiogram of Cardioform Deployment via right internal jugular vein *(Panel A)*. Transesophageal echocardiogram of full Cardioform Deployment *(Panel B)*.

output by Fick of 6.87 L/min and a left atrial pressure of 8mmHg.

An IMA catheter was advanced over a J-wire into the right atrium and the J-wire was then exchanged to an angle glidewire (Terumo®, Somerset, NJ). Under fluoroscopic and TEE guidance, the PFO was crossed with some difficulty using the glidewire into the left pulmonary vein. The IMA catheter was then exchanged to a 4Fr glide catheter (Terumo®) across the PFO tunnel into the pulmonary vein. The glidewire was then exchanged to a 300 cm 0.014 mailman guide wire (Boston Scientific, Marlborough, MA) and using the manipulation of the glide catheter, the wire was directed into the LV for better support and favorable angulation. The mailman wire was exchanged to Extrastiff 260 cm 0.038 Amplatzer wire (Cook Medical, Bloomington, IN). The glide catheter was removed carefully under fluoroscopic guidance. The Cardioform occluder was chosen because it is felt to have less risk of erosion and less rigidity to accommodate the anatomy as well as the delivery of the occluder. Due to the angulation, it was decided to use the 9Fr AGA Amplatzer Occluder deliver system (St. Jude Medical-St. Paul, MN) with modification to accommodate the Cardioform optimum delivery. The 30 mm Cardioform (WL. Gore Medical) was prepped in the usual manner and after carefully removing it from the delivery system; it was carefully advanced over into the LV via customized Amplatzer delivery system. Under fluoroscopic and TEE guidance, the cardioform was advanced and deployed across the PFO with excellent results (Figure 3a and Figure 3b). TEE showed successful closure of the PFO without shunt by color doppler (Figure 4). The cardioform was released and locking mechanism was confirmed (Figure 5). Several bubble saline injections were completed without signs of a residual shunt.

Three days later, she successfully underwent a minimal approach trans-femoral transcatheter aortic valve replacement (TF-TAVR) using a 23mm Sapien S3 valve (Edwards LifeScience) that was followed by her radical nephrectomy 5 days later with excellent result. During the 3 months follow up, she continues to do well.
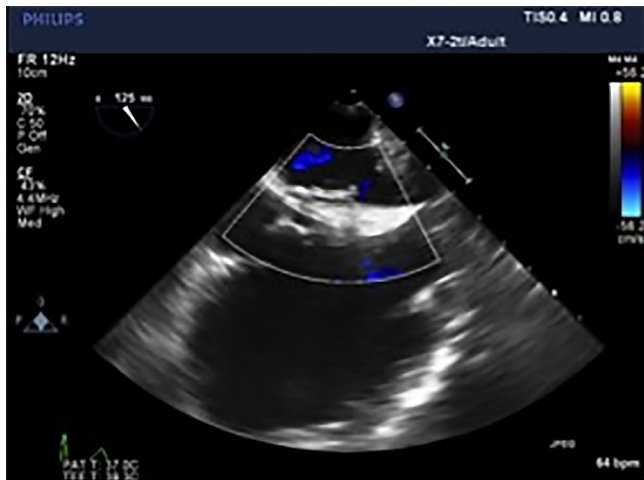
Figure 4. Transesophageal echocardiogram of the Cardioform device with color Doppler..
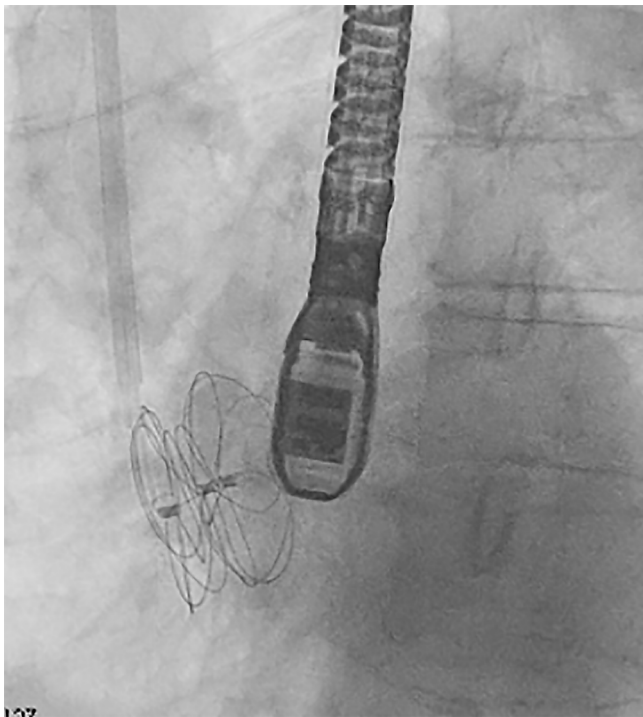

Figure 5. Radiographic image of Cardioform with transesophageal probe.

Discussion

Given the poor prognosis of patients with extended tumor thrombus from a renal cell carcinoma into the IVC, with rare yet potentially fatal risks of distal embolism particularly intraoperative, the diagnosis of RCC with IVC thrombus necessitates prompt eval-

uation and preoperative optimization [7]. Patients in that category with a PFO further warrant rapid coordination of a multidisciplinary team including structural interventional cardiologists to prepare appropriately selected patients for PFO closure before surgical resection of the RCC. Radical nephrectomy with IVC thrombectomy is considered to be the most effective therapeutic option in these patients [7].

The presence of severe AS in patients undergoing non-cardiac surgery (NCS) is often under-recognized and most available preoperative risk calculators do not account for it. The current American [6] and European [10] guidelines recommend AVR for patients with symptomatic severe AS; hence such patients' NCS should ideally be delayed. In our patient, given the time sensitivity of her RCC with an IVC thrombus, along with a very high risk of distal embolization with surgery, we decided to proceed with TAVR to better optimize her cardiovascular risk profile for higher chances of a cardiovascular event free radical nephrectomy.

In our case, decision had to be made with regards to her PFO and severe symptomatic AS in a patient with RCC and an extensive IVC thrombus as a means of optimization for her potentially curative radical nephrectomy. Due to thrombosis of the IVC, and successful case reports of using the R-IJ as the approach for PFO closure, we committed to using that approach. We chose the COD due to a lower erosion risk and ease of its delivery system manipulation given the curved anatomy through the internal jugular vein.

Furthermore, the use of multidisciplinary in-hospital teams has been shown to improve outcomes and improve patient satisfaction [11]. Our extensive discussions and detailed planning with the patient and her family, the team of oncologists, urologists, nephrologists, general surgeons, intensivists and nurses led to successful PFO closure and TAVR that optimized our patient for her curative radical nephrectomy and IVC thrombectomy.

Conclusion

To the best of our knowledge, this is the first case report of a successful transcatheter PFO closure with a COD through the R-IJ vein. It was also performed

as a primary prevention of embolic stroke in the setting of a known IVC thrombus in a patient with RCC before radical nephrectomy. This case illustrates the complexity and the significance of proper planning and multidisciplinary discussion to provide the best treatment and care plan particularly in patients with a PFO and symptomatic severe AS.

This is an important viable approach particularly in tertiary and quaternary referral centers that take care of similar cases for optimizing patients with malignancy for major potentially curative surgeries given that about 25% of the US population has a PFO [12].

Acknowledgement

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

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Case Report

Stenting the Snorkel: PCI of a Restenosed Left Main Stent Placed for Coronary Obstruction after Valve in Valve TAVR

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Abstract

Acute coronary artery occlusion is a known complication of transcatheter aortic valve replacement. One bailout strategy to treat acute coronary artery occlusion is deployment of a "snorkel" stent from the coronary artery behind the TAVR valve. While this approach will restore coronary artery patency, the long-term concern of this method is the ability to re-intervene on the stented coronary artery in the future. We demonstrate the complexity of re-intervention in a case of acute coronary syndrome due to ostial restenosis of a "snorkel" stent.

Key Words

TAVR • Left Main intervention • Percutaneous coronary intervention

Introduction

Transcatheter Aortic Valve Replacement (TAVR) is a well-established alternative to surgical aortic valve replacement for the treatment of aortic stenosis. As the indications for TAVR have expanded from prohibitive, high, and intermediate risk patients to clinical trials in low-risk patients, and as the overall population ages, the procedure is becoming increasingly common [1]. As such, it is important to be familiar with the possible risks of TAVR. A known risk of TAVR is coronary obstruction by the native valve (or bioprosthetic surgical valve) leaflets after deployment of the TAVR valve. Although the incidence is relatively uncommon (<1%), the consequence of acute coronary occlusion can be devastating, with a mortality risk as high as 40% [2, 3]. It is a risk that should be carefully considered and planned for during TAVR, especially if the coronary ostium originates less than 12 mm from the plane of the valve annulus, and particularly in the Medtronic self-expanding valves, which extend above the coronary ostia by design [4, 5]. The risk of coronary occlusion is increased for valve-in-valve procedures compared to native aortic valves and may be up to 3.5% [4]. Additionally, the height of the coronary ostium is not as straightforward a guide as in a native valve, due to the variable relationship between the native annulus and the bioprosthetic leaflets, and careful imaging is critical in order to understand the patient-specific anatomy [6]. The most common treatment strategy in the event of coronary obstruction during TAVR is PCI with stent deployment, and this is associated with a >90% success rate [4]. This is generally performed by pulling back and deploying a stent that has been pre-delivered to the coronary artery. Another novel option is intentional laceration of the aortic valve leaflet (BASILICA) [7]. With TAVR becoming increasingly common as the indications have expanded, so too will patients returning with coronary artery disease requiring intervention after TAVR.
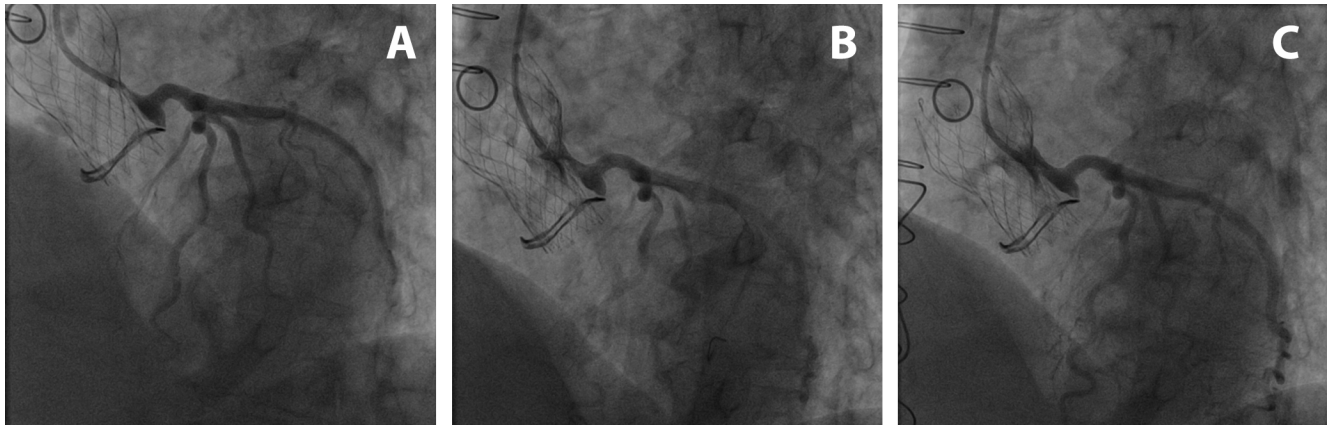
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Figure 1. Initial coronary angiogram demonstrating severe stenosis of the aorta to LM "snorkeled" stent *(Panel A)*. Subsequent coronary angiogram after initial stent placement *(Panel B)*. Final coronary angiogram after second stent placement *(Panel C)* .

Case Presentation

We present a case of a 71-year-old woman with coronary artery disease and aortic stenosis treated 10 years previously with single-vessel coronary artery bypass (SVG- RCA) and surgical aortic valve replacement with a 21 mm Mitroflow for non-rheumatic aortic valve stenosis. She then presented 8 years later with bioprosthetic valve degeneration and severe aortic regurgitation and underwent TAV-in-SAV with a 23 mm Medtronic Evolut R valve. Because of concern for left main (LM) occlusion with TAVR deployment due to a low take-off of the LM (8 mm from the plane of the annulus) a 4.0 x 15 mm Xience Alpine drug-eluting stent was positioned over a 0.014 Luge guidewire prior to valve placement. PEA arrest due to LM obstruction occurred immediately with TAVR deployment, and subsequently, the stent was pulled back and deployed in a snorkel fashion from the left main to the aorta behind the side struts of the Evolut R valve with the successful return of circulation and completion of the procedure.

The patient did well for two years but developed chest pain and progressive dyspnea on exertion. A pharmacologic PET stress test provoked chest pain and demonstrated marked ischemia in the LAD and LCx distribution. She was admitted for coronary angiography and possible intervention in the setting of the markedly abnormal stress test.

Coronary angiography was performed via right radial arterial access. The previously placed "snorkel"

stent in the LM was engaged with an EBU 3.5 guide catheter. Angiography demonstrated a 90% ostial in-stent stenosis at the location where the stent passed over the Mitroflow valve strut behind the Evolut R valve (Figure 1, Panel A). The stent and left main was wired with a Pilot 50 guidewire into the circumflex coronary artery. Intravascular ultrasound was performed in the LM with a Volcano Eagle Eye Platinum ultrasound catheter. The "snorkel" segment of the LM stent demonstrated a severe stenosis at the upper edge of the strut of the Mitroflow valve. The stenosis was predilated with an NC Sprinter 4.0 x 15 mm balloon, and a Xience Alpine 4.0 x 18 mm drug eluting stent was placed within the previous stent, extending through the cell of the Evolut R into the aorta. The stent was post-dilated with an NC Quantum Apex 4.5 x 15 mm balloon. We attempted to repeat IVUS imaging but were unable to fully advance the IVUS catheter over the Pilot 50 guide wire. The Pilot 50 wire was exchanged for a Wiggle wire through a Turnpike LP, and the IVUS catheter was able to be advanced into the stent. IVUS imaging demonstrated an ellipsoid shape to the new stent. (Figure 2, Panel A, Figure 1, Panel B) It was thought that increased radial strength was required to maintain stent patency against the external compression, and so a 4.0 x 12 mm Xience Alpine stent was placed and post-dilated with an NC Quantum Apex 5.0 x 12 mm balloon, inflated to 20 atmospheres. IVUS was repeated at the LM "snorkel" stent segment and demonstrated an improved, less ellipsoid geometry with an MLD of 5.0 x 3.5 mm
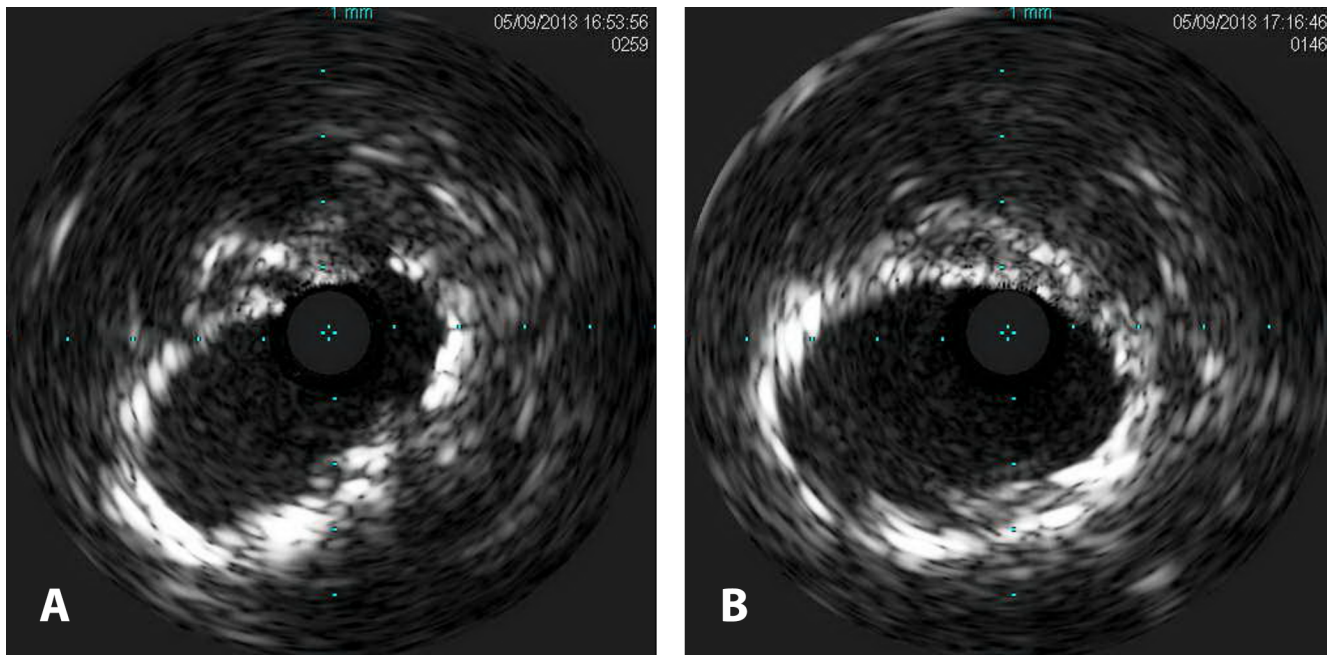
Figure 2. Intra vascular ultrasound demonstrating after initial stent placement demonstrating an ellipsoid geometry after initial stent placement *(Panel A)* and improved geometry after second stent placement *(Panel B)*.

(Figure 2, Panel B). The wire was removed and final angiography was performed (Figure 1, Panel C). The patient had an uneventful post-procedure recovery. She was chest pain-free at rest and with ambulation and was discharged home the next day.

Discussion

Avoidance of coronary occlusion is obviously the optimal approach whenever feasible with TAVR, and this requires careful imaging, planning, and device selection [8]. Planning for a bailout strategy for a patient at high risk of obstruction is critical. PCI with stent deployment can be employed to manage coronary occlusion in approximately 80% of patients [3]. The long-term concerns of a stent extruding into the aorta, especially behind the side cells of a TAVR valve, is stent patency and the ability to re-engage the stent for further treatment should this be necessary. A review of the literature demonstrates that, while PCI of the left main de novo prior to and after TAVR has been performed, this is the first published case of repeat intervention through a snorkeled LM stent [9, 10].

One alternative consideration for a treatment option was a surgical approach to revascularization, such as a single vessel LIMA rather than PCI. Given the complexity of this case, a heart team approach was taken with a full discussion between the referring cardiologist, the interventional cardiologist, and the cardiac surgeon regarding the best therapeutic approach. Her STS risk of mortality for the coronary bypass was calculated at 5.7%, driven largely by the acute progression of symptoms, prior cardiac surgery, cerebrovascular and peripheral arterial disease, gender, and morbid obesity.

The patient was deemed a poor surgical candidate, and it was determined that an attempt at PCI to resolve her ischemia was warranted rather than directly proceeding to bypass. If further restenosis develops in the LM stent segment then CABG will likely be required because of the complexity of the stent configuration in the LM coronary artery.

Another consideration for treatment when there is a concern for a low-lying coronary ostium would be the BASILICA procedure (Bioprosthetic Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction) [7]. This would involve the intentional laceration of the bioprosthetic (in this case) valve leaflet prior to TAVR deployment in order to attempt to prevent iatrogenic coronary artery ob-

struction. In our presented case, however, it is likely this would not have prevented the initial obstruction as the bioprosthetic valve strut was positioned at the ostium of the left main, and as such lacerating, the leaflet would likely not have prevented obstruction of the coronary ostium.

Conclusion

Given that the incidence of coronary artery disease in patients undergoing aortic valve replacement is as high as 30-50%, coronary intervention after TAVR is a relatively common and necessary procedure that has been demonstrated to be feasible [11]. With that in mind, this case presents a unique example of intervention in a "snorkeled" LM stent. While prevention of coronary obstruction during TAVR is the goal, PCI bailout is a reasonable strategy that should be considered and prepared for ahead of time in high-risk patients. Although challenging, reengagement and retreatment of such a "snorkeled" stent is feasible. However, the long-term outcomes of such interventions remain uncertain and will require further study.

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

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